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PATENT
Customer No. 22,852
Attorney Docket No. 6832.0062-00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Craig A. ROSEN et al.

Application No.: 10/775,204

Filed: February 11, 2004

For: ALBUMIN FUSION PROTEINS
COMPRISING GLP-1
POLYPEPTIDES

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Group Art Unit: 1653

Examiner: R. Wax

Confirmation No.: 1797

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(c)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(c), applicants bring to the attention of the Examiner the documents on the attached listing. This Information Disclosure Statement is being filed after the events recited in Section 1.97(b) but, to the undersigned's knowledge, before the mailing date of either a Final action, Quayle action, or a Notice of Allowance. Under the provisions of 37 C.F.R. § 1.97(c), this Information Disclosure Statement is accompanied by a fee of \$180.00 as specified by Section 1.17(p).

Copies of the listed foreign and non-patent literature documents are attached.

Copies of the U.S. patent publications are not enclosed. Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

05/27/2005 HAL111 00000108 10775204

180.00 OP

01 FC:1806

English translations of the following non-English patent documents are enclosed with the relevant documents:

Documents cited in the 45-page Information Disclosure Statement by Applicants

JP 2 227079,
JP 3 201987,
WO 93/00437,
WO 93/15200,
WO 95/30759,
WO 99/15193.

English translations of the following non-English articles cited in the 45-page Information Disclosure Statement by Applicants are also enclosed with the relevant documents:

Becquart, J., "Les Syncopes ou Malaises D'Origine Vasculaire," *Soins*, 504: 4-8 (1987);

Becquart J., et al., "Pronostic du Syndrome de Wolff-Parkinson-White chez le Nourrisson," *Arch. Mal. Coeur* 81:695-700 (1988);

Becquart, J., et al., "Insuffisance Aortique Argue Rhumatoide Traitee Par un Remplacement Valvulaire," *Arch. Mal. Coeur* 84:987-989 (1991);

Becquart, J., et al., "Les Pheochromocytomes Malins," *Annales De Cardiologie Et D'Andeliologie*, 36:191-196 (1987);

Cai, M. et al., "Development and Application of Hybridoma Secreting Monoclonal Antibody Against Poly-Human Serum Albumin" *J. WCUMS* 20(2):134-136 (1989);

Chen, Y-M., "Pulmonary Nocardiosis with Cerebral Abscess Successfully Treated by Medication Alone—A Case Report," *Chin. Med. J. (Taipei)* 47:294-298 (1991);

Chen, Y-M., et al., "Neurofibromatosis with Interstitial Pulmonary Fibrosis—Case Report and Literature Review," *Chin. Med. J. (Taipei)* 42:213-218 (1988);

Chen, Z., et al., "Enhancing the Immunogenicity of the preS Antigen of Hepatitis B Virus by Genetically Fusing it with Interleukin-2," *Natl. Med. J. China* 76(1):34-37 (1996);

Dmitrenko, V.V., et al., "Heterogeneity of the Polyadenylation Site of mRNA Coding for Human Serum Albumin," *Genetika* 26(4):765-769 (1990);

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- Grebnyuk, V.N., et al., "Investigation of Safety, Reactivity and Therapeutic Efficacy of Ointment Containing Porcine Leukocytic Interferon," *Antibiotiki* 3:145-149 (1981);
- Hannebicque, G., et al., "Manifestations Cardiaques De La Maladie De Lyme," *Ann. Cardiol. Angelol.* 38:87-90 (1989);
- Huang S-Z., et al., "A Study of Transgenic IFV Cattle with the Human Serum Albumin Gene Integrated," *ACTA Genetic Sinica* 27(7):573-579 (2000);
- Hwang, G-S., et al., "Small Bowel Perforation Secondary to Metastatic Pulmonary Carcinoma," *Chin. Med. J. (Taipei)* 41(2):159-164 (1988);
- Le Bras, M., et al., "Epidemiologie et Clinique des Maladies Tropicales D'importation," *La Revue de Medicine Interne* 13:205-210 (1992);
- Matsuda, Y., et al., "Human Serum Albumin Variants," *Tanpakushitu Kakusan Koso* 33(5):930-935 (1988);
- Ohtani, W., et al., "Structure of Recombinant Human Serum Albumin from *Pichia pastoris*," *J. Pharm. Soc. Japan* 117(4):220-232 (1997);
- Ruzgas, T.A., et al., "Ellipsometric Study of Antigen-Antibody Interaction at the Interface Solid/Solution," *Biofizika*, 37 (1): 56-61 (1992);
- Takeshima, K., et al., "Ligand Binding Properties and Esterase-like Activity of Recombinant Human Serum Albumin," *Regular Articles Yakugaku Zasshi* 116(8):622-629 (1996);
- Thery, C., et al., "Filter Cave Temporaire Permettant le Diagnostic et al Fibrinolyse Chez les Patients Suspects d'embolie Pulmonaire Massive," *Arch. Mal. Coeur* 84:525-530 (1991);
- Vincent, M.P., et al., "Surdosage a l'halofantrine," *La Presse Medicale* 3:131 (1992);
- Yeh, P-F., et al., "Haemophilus Infection in Chronic Obstructive Pulmonary Disease Patients," *Chin. Med. J. (Taipei)*, 44:57-60 (1989);
- Yeh, P-F., et al., "Tuberculosis Bacteremia," *China Med. J. (Taipei)* 47(4):290-293 (1991).
- Zhong, S., et al., "Experimental Research on Inhibition of Hepatitis B Virus of Targeted Hepatocytes In Vitro by Antisense Oligonucleotides," *National Medical Journal of China* 75(7):392-395 (1995);

Zhou, C.S., et al., "A Monoclonal Antibody Directed Against an Enediyne Antitumor Antibiotic and its Preliminary Application," *ACTA Pharmaceutica Sinica* 32(1):28-32 (1997).

In lieu of English translations and as a concise statement of relevance of each, English language Derwent abstracts of the following non-English patent documents are enclosed with the following documents:

Documents cited in the 45-page Information Disclosure Statement by Applicants

JP 1 117790,
CN 1235981 A,
CN 1239103 A,
JP 2 117384,
JP 3 27320,
JP 4 211375,
JP 5 292972,
JP 6 38771,
JP 6 22784,
JP 8 53500,
JP 8 59509,
JP 8 51982.

Documents cited in the Supplemental Information Disclosure Statement by Applicants (2)

DE 19921537
WO 03/003971,
WO 92/01055,
WO 91/05052.

In lieu of a translation or statement of relevance, English-language patent equivalents and patent family information have been submitted for the following non-English patent documents:

Documents cited in the 45-page Information Disclosure Statement by Applicants

EP 0 236 210 A1 (equivalent to U.S. Pat. Nos., 5,100,784 and 5,187,261),
EP 0 511 912 A1 (equivalent to U.S. Pat. No. 5,646,012),
EP 0 711 835 A1 (equivalent to U.S. Pat. No. 6,114,146),
FR 2,635,115 (equivalent to EP 0 361 991 A2),
FR 2,719,593 (equivalent to WO 95/30759, translated as above),
DE 37 23 781 A1 (equivalent to UK Pat. Application No. GB 2 193 631 A),

WO 93/15199 (equivalent to U.S. Pat. No. 5,876,969),
WO 93/15211 (equivalent to U.S. Pat. No. 5,665,863),
WO 96/14409 (equivalent to AU Pat. No. 704,594),
WO 96/14416 (equivalent to U.S. Pat. No. 6,149,911).

Documents cited in the Supplemental Information Disclosure Statement by Applicants (2)

WO 82/02715 (equivalent to EP 0 070 906 A1),
WO 98/47489 A1 (equivalent to AU 741964 B2),
WO 99/28346 A1 (equivalent to CA 2309810 A1),
EP 0 106 179 B1 (equivalent to US 4,490,289),
EP 0 347 781 B1 (equivalent to CA 1341211).

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claims in the application and applicants determine that the cited documents do not constitute "prior art" under United States law, applicants reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: May 26, 2005

By: Charles E. Van Horn
Charles E. Van Horn
Reg. No. 40,266

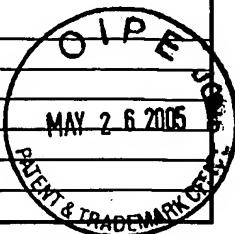
**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

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Complete if Known

Application Number	10/775,204
Filing Date	February 11, 2004
First Named Inventor	Craig A. Rosen et al.
Art Unit	1653
Examiner Name	Robert Wax
Attorney Docket Number	6832.0062-00

**U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS**

Examiner Initials*	Cite No.	Document Number	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code (if known)			
		4,336,248	06/22/1982	Bonhard et al.	
		4,751,180	06/14/1988	Cousens et al.	
		4,765,980	08/23/1988	DePrince et al.	
		4,801,575	01/31/1989	Pardridge et al.	
		4,914,027	04/03/1990	Knapp et al.	
		4,959,314	09/25/1990	Mark et al.	
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		5,045,312	09/03/1991	Aston et al.	
		5,073,627	12/17/1991	Curtis et al.	
		5,100,784	03/31/1992	Latta et al.	
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		5,116,964	05/26/1992	Capon et al.	
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		5,223,408	06/29/1993	Goeddel et al.	
		5,272,070	12/21/1993	Lehrman et al.	
		5,302,697	04/12/1994	Goodey et al.	
		5,330,971	07/19/1994	Wells et al.	
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		5,380,712	01/10/1995	Ballance et al.	
		5,612,196	03/18/1997	Becquart et al.	

Examiner Signature		Date Considered	
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

**INFORMATION DISCLOSURE
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(Use as many sheets as necessary)

Sheet	2	of	45	<i>Complete if Known</i>
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				<i>Art Unit</i> 1653
				<i>Examiner Name</i> Robert Wax
				<i>Attorney Docket Number</i> 6832.0062-00

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS

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		Number-Kind Code (<i>if known</i>)			
		5,641,663	06/24/1997	Garvin et al.	
		5,646,012	07/08/1997	Fleer et al.	
		5,665,863	09/09/1997	Yeh et al.	
		5,679,777	10/21/1997	Anderson et al.	
		5,705,363	01/06/1998	Imakawa et al.	
		5,714,377	02/02/1998	Tanner et al.	
		5,766,883	06/16/1998	Ballance et al.	
		5,844,095	12/1/1998	Linsley et al.	
		5,876,969	03/02/1999	Fleer et al.	
		5,889,144	03/30/1999	Alila et al.	
		5,948,428	09/07/1999	Lee et al.	
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		6,114,146	09/05/2000	Herlitschka et al.	
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		2005-0037022	02/17/05	Rosen et al.	

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		2004-0171123	09/02/2004	Rosen et al.	
		2004-0086977	05/06/2004	Fleer et al.	
		2004-0086976	05/06/2004	Fleer et al.	
		2004-0010134	01/15/2004	Rosen et al.	
		2003-0219875	11/27/2003	Rosen et al.	
		2003-0199043	10/23/2003	Ballance et al.	
		2003-0171267	09/11/2003	Rosen et al.	
		2003-0125247	07/03/2003	Rosen et al.	
		2003-0104578	6/5/2003	Ballance	
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		2003-0022308	1/30/2003	Fleer et al.	
		10/922,142		Rosen et al.	
		09/833,111		Rosen et al.	

Note: Copies of the U.S. Patent Documents are not Required in IDS filed after October 21, 2004

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				Examiner Name	Robert Wax
				Attorney Docket Number	6832.0062-00

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Country	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation
		Number Kind Code (if known)				
		0 073 646 A2	03/09/1983	EPO		
		0 079 739 A2	05/25/1983	EPO		
		0 088 632 A2	09/14/1983	EPO		
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		0 236 210 A1	09/09/1987	EPO		English Equivalent
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		0 314 317 A1	05/03/1989	EPO		
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		0 322 094 A1	06/28/1989	EPO		
		0 325 262 A2	07/26/1989	EPO		
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		0 511 912 A1	11/04/1992	EPO		English Equivalent

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		Number Kind Code (if known)				
		0 711 835 A1	05/15/1996	EPO		English Equivalent
		0 771 871 A2	07/05/1997	EPO		
		1 117790	05/10/1989	Japan		Abstract
		1235981A	11/24/1999	China		Abstract
		1239103A	12/22/1999	China		Abstract
		2 117384	05/01/1990	Japan		Abstract
		2 193 631 A	02/17/1988	UK		
		2 227079	09/10/1990	Japan		Yes
		2 350 362 A	11/29/2000	UK		
		2 635 115	09/06/1990	France		English Equivalent
		2 719 593	11/10/1995	France		English Equivalent
		2022539	02/04/1991	Canada		
		3 201987	09/03/1991	Japan		Yes
		3 27320	02/05/1991	Japan		Abstract
		37 23 781 A1	01/21/1988	Germany		English Equivalent
		4 211375	08/03/1992	Japan		Abstract
		5 292972	11/09/1993	Japan		Abstract
		6 38771	02/15/1994	Japan		Abstract

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		Number Kind Code (if known)				
		6-22784	02/01/1994	Japan		Abstract
		704594	05/31/1995	Australia		
		8 53500	02/27/1996	Japan		Abstract
		8 59509	03/05/1996	Japan		Abstract
		8-51982	02/27/1996	Japan		Abstract
		WO 00/04171	01/27/2000	PCT		
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		WO 89/02922	04/06/1989	PCT		
		WO 90/04788	05/03/1990	PCT		
		WO 90/13653	11/15/1990	PCT		
		WO 91/02754	03/07/1991	PCT		
		WO 91/08220	06/13/1991	PCT		
		WO 93/00109	01/07/1993	PCT		
		WO 93/00437	01/07/1993	PCT		Yes
		WO 93/03164	02/18/1993	PCT		
		WO 93/15199	08/05/1993	PCT		English Equivalent
		WO 93/15200	08/05/1993	PCT		Yes

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		WO 94/25489	11/10/1994	PCT		
		WO 95/23857	09/08/1995	PCT		
		WO 95/27059	10/12/1995	PCT		
		WO 95/30759	11/16/1995	PCT		Yes
		WO 96/03144 A1	02/08/1996	PCT		
		WO 96/08512	03/21/1996	PCT		
		WO 96/14409	05/17/1996	PCT		English Equivalent
		WO 96/14416	05/17/1996	PCT		English Equivalent
		WO 96/18412	06/20/1996	PCT		
		WO 97/24445	07/10/1997	PCT		
		WO 97/34997	09/25/1997	PCT		
		WO 97/39132	10/23/1997	PCT		
		WO 98/04718	02/05/1998	PCT		
		WO 98/36085	08/20/1998	PCT		
		WO 99/00504	01/07/1999	PCT		
		WO 99/13914	03/25/1999	PCT		
		WO 99/15193	04/01/1999	PCT		Yes

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				Filing Date	February 11, 2004
				First Named Inventor	Craig A. Rosen et al.
				Art Unit	1653
				Examiner Name	Robert Wax
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FOREIGN PATENT DOCUMENTS

Examiner Initials ⁵	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Country	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation
		Number Kind Code (<i>if known</i>)				
		WO 99/66054	12/23/1999	PCT		
		WO 02/46227	6/13/2002	PCT		

NON PATENT LITERATURE DOCUMENTS

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		ABASTADO, J-P., et al., "A Soluble, Single Chain K ^d Molecule Produced by Yeast Selects a Peptide Repertoire Indistinguishable from that of Cell-surface-associated K ^d ," <i>Eur. J. Immunol.</i> , 23:1776-1783 (1993).	
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		ARMSTRONG, J.D., et al., "Opioid Control of Growth Hormone in the Suckled Sow is Primarily Mediated Through Growth Hormone Releasing Factor," <i>Domestic Animal Endocrinology</i> 7:191-198 (1990).	
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		BECQUART, J., et al., "Les Pheochromocytomes Malins," <i>Annales De Cardiologie Et D'Andrologie</i> , 36:191-196 (1987), with English translation.	Yes

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<i>First Named Inventor</i>	Craig A. Rosen et al.
<i>Art Unit</i>	1653
<i>Examiner Name</i>	Robert Wax
<i>Attorney Docket Number</i>	6832.0062-00

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		GHANDEHARI, H., et al., "Size-Dependent Permeability of Hydrophilic Probes Across Rabbit Colonic Epithelium," <i>The Jour. of Pharmacology and Experimental Therapeutics</i> 280:747-753 (1997).	
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Application Number	10/775,204
Filing Date	February 11, 2004
First Named Inventor	Craig A. Rosen et al.
Art Unit	1653
Examiner Name	Robert Wax

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				Examiner Name Robert Wax
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				<i>Examiner Name</i> Robert Wax
				<i>Attorney Docket Number</i> 6832.0062-00

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Sheet	39	of	45	Complete if Known
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				First Named Inventor Craig A. Rosen et al.
				Art Unit 1653
				Examiner Name Robert Wax
				Attorney Docket Number 6832.0062-00

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IDS Form PTO/SB/08: Substitute for form 1449A/PTO				Complete if Known	
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<i>Attorney Docket Number</i>	6832.0062-00			

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		TZANELA, M., et al., "Recombinant Human Growth Hormone-Binding Protein Fails to Enhance the <i>in Vivo</i> Bioactivity of Human Growth Hormone in Normal Rats," <i>Endocrinology</i> , 108(12): 5316-5324 (1997).		
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		WHITTINGTON, H., et al., "Expression of the <i>Aspergillus niger</i> glucose Oxidase gene in <i>A. niger</i> , <i>A. nidulans</i> and <i>Saccharomyces cerevisiae</i> ," <i>Current Genetics</i> 8:531-536 (1990).	
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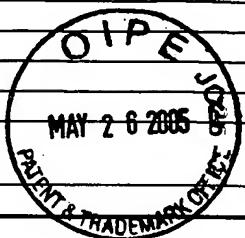
**SUPPLEMENTAL INFORMATION
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Complete if Known

Application Number	10/775,204
Filing Date	February 11, 2004
First Named Inventor	Rosen et al.
Art Unit	1653
Examiner Name	Robert Wax

**U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS**

Examiner Initials	Cite No.	Document Number	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code (if known)			
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		US-5,010,003	04/23/1991	Chang et al.	
		US-5,260,202	11/09/1993	Clarke et al.	
		US-5,272,070	12/21/1993	Lehrman et al.	
		US-5,395,922	03/07/1995	Bjørn et al.	
		US-5,409,815	04/25/1995	Nakagawa et al.	
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		US-5,641,663	06/24/1997	Garvin et al.	
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Note: Copies of the U.S. Patent Documents are not Required in IDS filed after October 21, 2004

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		Country Code Number Kind Code (if known)				
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Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation
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<i>First Named Inventor</i>	Rosen et al.
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<i>Examiner Name</i>	Robert Wax

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NON PATENT LITERATURE DOCUMENTS

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Application Number	10/775,204
Filing Date	February 11, 2004
First Named Inventor	Craig A. Rosen et al.
Art Unit	1653
Examiner Name	Robert Wax

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS

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		Number-Kind Code (if known)			
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Art Unit	1653
Examiner Name	Robert Wax

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS

Examiner Initials	Cite No.	Document Number	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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**SUPPLEMENTAL INFORMATION
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STATEMENT BY APPLICANT (2)**

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Sheet	5	of	19	Attorney Docket Number	6832.0062-00
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Complete if Known

Application Number	10/775,204
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Note: Copies of the U.S. Patent Documents are not Required in IDS filed after October 21, 2004

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Examiner Name	Robert Wax

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Examiner Name	Robert Wax

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